MIRD No. 412552-15

DATA EVALUATION RECORD

1. **CHEMICAL:** ortho-Phthalaldehyde
Shaughnessey No. 129017.

2. **TEST MATERIAL:** ortho-Phthalaldehyde Technical 99% A.I. (Cidex™)

3. **STUDY TYPE:** Avian Acute Oral Toxicity Test
Species used: Mallard Duck

4. **STUDY ID:** Fletcher, D. W. and C. A. Pedersen. 1989. O-Phthalaldehyde: 28-Day Acute Oral LD_{50} Study in Mallard Ducks. Bio-life Associates, Ltd., Neillsville, WI for Surgikos, Inc. Arlington, TX.

5. **REVIEWED BY:**

Clyde R. Houseknecht
Wildlife Biologist
EEB/EFED

Signature: Clyde R. Houseknecht
Date: 1/4/90

6. **APPROVED BY:**

Henry T. Craven, Head
Review Section #4
EEB/EFED

Signature: Henry T. Craven
Date: 1/5/90

7. **CONCLUSIONS:** The acute oral LD_{50} value of ortho-Phthalaldehyde for mallard ducks was determined to be 738 (95% C.L. 390 - 1,763) mg active ingredient / kg. The no observed effect level was <316mg/kg. Thus, ortho-Phthalaldehyde is slightly toxic to this species.

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:** N/A

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A

11. **MATERIALS AND METHODS:**

A. **Test Animals:** Mallard ducks were obtained from a commercial source in Illinois. All birds were pen-reared and were phenotypically indistinguishable from wild birds. Test animals were 18 weeks of age and ranged in weight from 856-1286 g at study initiation. Each treatment and control group contained five males and five females. All birds were acclimated to the caging and facilities for 25 days prior to the initiation of the study.

Throughout acclimation and testing all test birds were fed Purina Duck Grower W/O ration. Food and water were provided ad libitum. Birds were fasted for 19 to 20 hours prior to dosing. They received no medication during the study.

B. **Test System:** The test substance was administered via gelatin capsules at hour 0 on test day 1. Each control bird received two empty gelatin capsules.

Groups of ten ducks were assigned to each of the treatment groups and the control group by random draw. Each test bird was weighed and dosed on the basis of milligrams of test substance per kilogram of body weight. Birds were housed indoors in batteries of pens each of which had a floor space that measured approximately 122 X 122 cm. Each dosing group was assigned to two pens. Birds were maintained at ambient room temperature ranging from 49 - 83°F. The photoperiod was eight hours of light throughout the study.

C. **Dosage:** The test consisted of a geometric series of five dosage groups and a control group. Nominal dosages were 316, 464, 681, 1,000 and 1,470 mg a.i./kg of body weight.

D. **Design:** Avian, single dose, oral LD_{50}.

E. **Statistics:** The authors calculated an LD_{50} value of 810 mg a.i./kg using the technique of Litchfield and Wilcoxon.

12. **REPORTED RESULTS:** There was no mortality in the control group. Ten percent, 60%, 40%, 60% and 70% of test birds died in treatment groups one to five respectively. Signs of toxicity included lethargy, regurgitation, general weakness, and anorexia. Three regurgitated gelatin capsules were found under the pen of the highest dosage group within nine minutes after dosing.

13. **STUDY AUTHOR'S CONCLUSION/QUALITY ASSURANCE MEASURES:**

13. **STUDY AUTHOR'S CONCLUSION/QUALITY ASSURANCE MEASURES:** The mallard duck acute oral LD_{50} value for O-Phthalaldehyde was determined to be 870 mg a.i./kg. The no effect level was <316 mg a.i./kg. Bio-life Associates warrants that this study conforms with Good Laboratory Practices as published by the U.S. Environmental Protection Agency.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedures:** The procedures were in accordance with EPA's Standard Evaluation Procedure for Avian Single Dose Oral LD_{50}.

B. **Statistical Analysis:** Mortality data were reanalyzed with the E.P.A.'s Toxinal program. The probit method yielded an LD_{50} value of 738 (95% C.L. 390 - 1,763) mg a.i./kg.

C. **Discussion/Results:** The acute, oral LD_{50} of ortho-phthalaldehyde to mallard ducks is 870 mg/kg.

D. **Adequacy of the Study:**

(1) **Classification:** Core

(2) **Rationale:** N/A

(3) **Repairability:** N/A

15. **COMPLETION OF ONE-LINER:** Yes, December 18, 1989